UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL DOCKET NO. 1456 Master File No. 01-CV-12257 Subcategory Case No. 06-CV-11337
THIS DOCUMENT RELATES TO:	)	Judge Patti B. Saris
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., No. 06-CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc., et al., No. 05-CV-11084-PBS; and	)	
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp. et al., No. 07-CV-10248-PBS	)	

COMBINED MEMORANDUM OF DEFENDANTS
ABBOTT LABORATORIES INC.,
DEY, INC., DEY, L.P., DEY L.P., INC.,
BOEHRINGER INGELHEIM ROXANE, INC. AND ROXANE LABORATORIES, INC.
IN OPPOSITION TO THE UNITED STATES' CROSS-MOTIONS
FOR PARTIAL SUMMARY JUDGMENT

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INTRODUCTION

Nearly 15 years of discovery for the Government and over 100 depositions have revealed that Medicare and state Medicaid programs that used AWP to reimburse for drugs did so with eyes wide open. Indeed, though these cases turn on DOJ's theory that the Government was actually deceived by AWPs, DOJ cites not a single CMS official who espouses that view. To the contrary, myriad federal and state officials, who have long known that the multiple-source drugs in these cases were sold at discounts of 90% or more below AWP, have testified that they deliberately paid more than acquisition cost for these drugs. And they did so for legitimate policy reasons, including encouraging generic substitution, subsidizing inadequate or non-existent dispensing fees, and ensuring beneficiaries access to care.

DOJ's brief ignores this record entirely, and impermissibly begs the Court to do the same. DOJ's attempt to keep this evidence from the jury, which hinges on an appeal to this Court's prior "plain meaning" ruling, falls flat. That ruling was based in large part on an "*amicus*" brief, which DOJ itself submitted as the purported official position of HHS, and which has now been proven false. And in any event, the ruling emanated from this Court's role as trier-of-fact in a lawsuit involving branded drugs and a much more limited evidentiary record—largely because DOJ invoked the Touhy regulations to bar the very evidence that would contradict its "*amicus*" brief. These cases, involving generic drugs and evidence of widespread knowledge of federal and state officials of the nature of AWP, are far different. If anything, this Court's prior decisions preclude summary judgment for DOJ precisely because they establish that program administrators' expectations regarding AWP are crucial. Here, juries must decide whether any failure to pay acquisition cost resulted from Defendants "fooling" officials, or instead, as the record makes plain, from deliberate policy decisions.

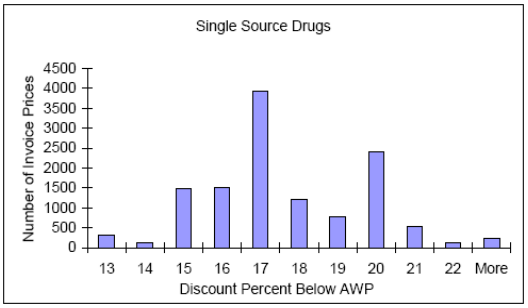
Even as DOJ asks this Court to hold Defendants liable in the face of significant contrary

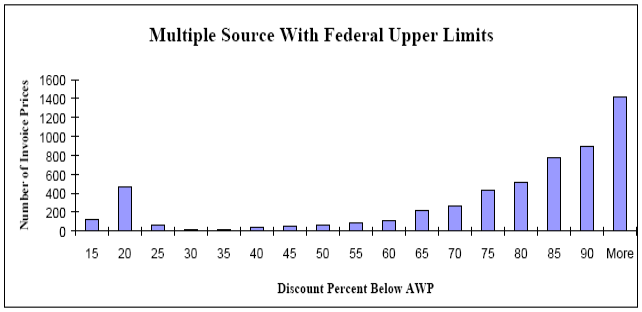
evidence, DOJ also opposes Defendants' motions for partial summary judgment, without any law or evidence to support its claims. This turns the world on its head. Partial summary judgment should enter in Defendants' favor, as detailed below and in their individual briefs.

BACKGROUND

A. The Market For And Pricing Behavior Of Multiple-Source Drugs Differ Dramatically From Branded Drugs.

The market for multiple-source drugs is dramatically different from the market for branded drugs. Prices for multiple-source or "generic" drugs fluctuate because of intense competition between manufacturers. (CF ¶¶ 1-3, 11-13.)[1] This results in varying levels of discounts, with contract purchasers and some classes of trade receiving extremely deep discounts. (*Id.*) In this market, published AWPs bear no predictable relationship to market prices. OIG demonstrated this in 1999, when it collected invoices showing that the discount off of AWP paid for branded drugs (15-20%) differed radically from generic drugs (usually over 80%, with the greatest percentage over 90%) (CF ¶ 9):





Luis Cobo (Ven-A-Care's former President and a prior owner of a retail pharmacy), Dr. Bruce Vladeck (Administrator of CMS from 1992 to 1997), Paul Chesser (Office of the Inspector General), and many others confirmed that multiple-source drugs have been priced

[1] Citations are as follows: *United States' Common Memorandum of Law in Support of Cross-Motions for Partial Summary Judgment And In Opposition To The Defendants' Motions For Summary Judgment*, Dkt. No. 6317, as (DOJBr. at __.); Defendants' *Combined Local Rule 56.1 Statement Of Additional Material Facts Pertinent To The United States' Motions For Partial Summary Judgment Against Defendants*, filed herewith, as (CF ¶ __.).

differently than branded drugs since at least the early 1980s, such that even "mega-spreads" are common and expected. (*Id.* ¶¶ 1, 11, 40.) Such pricing differentials are predictable when manufacturers compete. In contrast, manufacturers of branded drugs have monopoly power to set prices. (*Id.* ¶ 12.)

Because of this fundamental difference in the pricing behavior of brands and generics, the officials who established drug pricing policy at CMS and at the various state Medicaid programs fully expected published prices, including AWPs, to bear no relation to acquisition cost for multiple-source drugs. (*Id.* ¶¶ 1-3.) Tennessee's Leo Sullivan put it aptly:

> Q. Did you believe that you could shave 20, 30 percent off of [AWP] and get a reliable number of what pharmacies and physicians actually paid for drugs.
>
> A. Well, it would, *it would depend on—I mean, are we talking brand or generic*?
>
> Q. Both right now. Would you draw a distinction?
>
> A. Oh, yeah. Yeah. . . . The generic drugs, you know, *you could pay AWP minus 80 percent and still the pharmacist makes money for some*, I assume. But AWP minus 25 might be below cost for a brand name drug for a rural pharmacy that has a very small volume. Okay? So there is, there is a difference between brand and generic. . . . *But to say 20-30 percent, use that number, you would have to distinguish between brand and generic.*

(*Id.* ¶ 1(a); *see generally id.* ¶ 1.) The Government's own expert, Dr. Stephen Schondelmeyer, likewise recognizes that there is no "consistent relationship" between "actual acquisition cost" and published AWPs for "multiple-source (generic) drug products." (*Id.* ¶ 12.)

For these reasons, the Court cannot just apply here the "expectations yardstick" for the published price of branded drugs that it adopted while sitting as the trier of fact in an earlier consumer fraud class action. *See In re Pharm. Ind. Avg. Wholesale Price Litig.*, 491 F. Supp. 2d 20, 39-41, 76-78, 86-92 (D. Mass. 2006). That conclusion was based exclusively, and expressly, on evidence concerning branded (not generic) drugs. *See id.* at 87-88. In these cases, juries will have to determine what CMS and state Medicaid programs expected for the multiple-source

drugs at issue. On this issue there are (at a minimum) genuine issues of material fact.

B. Multiple-Source Drug Payments Under Medicaid.

1. Medicaid Payment Rules Differ from State To State, And Federal Regulations Allow States To Pay More Than Acquisition Cost For Individual Drugs And Prescriptions.

Medicaid programs are primarily designed by individual states. Relevant state and federal officials agree that the law provides states maximum flexibility to design their systems. (*E.g.*, CF ¶¶ 16-19, 23.) As several witnesses testified: "If you've seen one Medicaid program, you've seen one Medicaid program." (*Id.* ¶¶ 18(c) & (d), 19(a) & (b).) In particular, Medicaid payment rates are determined by each state. As Tom Scully (former Administrator of CMS) testified, states set drug payment rates based on "local politics"; it is not the "role of the CMS administrator to go in and tell states what they have to pay." (*Id.* ¶¶ 20-21.)[2] Accordingly, for Medicaid claims, each state's policy controls.[3]

CMS reviews state plans to determine whether a state is entitled to federal matching funds by determining whether *in the aggregate* the state state pays no more than permitted by federal regulations. (*Id.* ¶¶ 24-28.) Contrary to DOJ's statement that "federal regulations called for a state Medicaid program to pay the estimated acquisition cost of *the drug*, along with a reasonable dispensing fee" (*see* DOJBr. at 11) (emphasis added), to meet the federal law "in the aggregate" standard, states may pay more than the EAC or FUL for any single drug, so long as

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[2] Opposing a lawsuit seeking to enjoin CMS's proposed FUL regulations in 2007, DOJ itself argued that the "[s]tates—not the federal government—set the rate at which they pay pharmacies." (*Id.* ¶ 22.) The Federal Government merely "*helps* states provide covered services to Medicaid-eligible beneficiaries," "pays *nothing* to pharmacies for the prescription drugs those pharmacies distribute to Medicaid patients, does not dictate the formula states may use to determine the amount they will pay pharmacies, and does not prescribe limits on the state payments to pharmacies." (*Id.*)

[3] *See, e.g.*, 11/13/2008 Tr. at 10 ("[I]t is unbelievably fact-intensive and difficult to go through what the Medicaid policies are. It is not just a question of law. It's who knew what, how did it happen, when did the policies change? . . . [I]t's going to be state by state: What did they know, when did they know it, what was the statutory scheme?").

the total spent by each state program meets federal regulatory requirements. (*Id.*) The plain language of the EAC regulation shows that drug payments "in the aggregate" refer to all payments for *all* drugs. Specifically, for drugs for which no Federal Upper Limit ("FUL") has been set, the state may pay no more than the estimated acquisition cost ("EAC") *in the aggregate*. (*Id.* ¶ 25); 42 C.F.R. § 447.331(a). Likewise, for drugs subject to a FUL, the state may pay no more than the FUL for those drugs *in the aggregate.* (*Id.* ¶ 25); 42 C.F.R. § 447.331(b) (emphasis added).

As CMS widely reported when the regulation was promulgated in 1987, "the individual prices set by the Medicaid agencies, may exceed federal levels for some drugs." (CF ¶¶ 27-28.)

- CMS official Dennis Smith testified that this permits a state to pay more than EAC for one drug, as long as it makes up that difference elsewhere. (*Id.* ¶ 29.)
- Larry Reed, CMS's 30(b)(6) witness on the EAC regulation, could not point to "any federal regulation that would prohibit a state from paying a margin or a spread on a particular drug," nor any regulation that "prohibits a state from paying more than its best estimate for a particular drug." (*Id.* ¶ 30.) Thus, for example, Reed could identify nothing in the EAC regulation that "would prevent a state Medicaid pharmacy administrator . . . from paying a margin or profit above acquisition cost for generic drugs." (*Id.*; *see also id.* ¶ 32.)

Moreover, the 1987 regulation setting the EAC rule was carefully drafted to allow "estimated acquisition cost" and the "reasonable dispensing fee" to be measured *together*, not separately, when meeting the "in the aggregate" requirement. 42 C.F.R. § 447.331(a), (b). The preamble notes that the pre-existing "EAC method of payment will be eliminated," and that a state could forego payment of a separate dispensing fee altogether under the new aggregated standard. 52 Fed. Reg. 28651, 28653, 28654. That could happen, of course, only if the ingredient cost and dispensing fee are measured together "in the aggregate." Dr. Robert Helms, head of the HHS Task Force that oversaw drafting the regulation, confirmed that this regulation codified the well-recognized state practice of cross-subsidization between ingredient cost and

dispensing fee. (*Id.* ¶¶ 33-34.)

The HHS Departmental Appeals Board ("DAB") concurs in this interpretation of the "in the aggregate" standard, concluding in numerous opinions that the regulation allows cross-subsidization.[4] For example, in 1992 the DAB held:

> Section 447.333(b) of 42 C.F.R. provides in pertinent part that a state's drug payments may not exceed "in the aggregate" the specific limits established by HCFA for each drug plus a reasonable dispensing fee for each drug. Since the focus of the regulations is on a state's overall payment level, *the State could reasonably have concluded that it could offset a lower than reasonable dispensing fee with ingredient costs which were lower than HCFA's specific limits as well as higher than the costs to the pharmacies themselves*.

(*Id.* ¶ 36.) (emphasis added). The DAB also referenced an earlier ruling, where it stated: "The regulation can reasonably be read *to permit states to pay more than an appropriately determined EAC for drug ingredient costs, but less than a reasonable dispensing fee, so long as payments did not, in the aggregate, exceed the upper limit*." (*Id.*) (emphasis added).

2. There Are Genuine Issues Of Fact As To Whether Any State (Let Alone All Of Them) Intended To Pay Actual Acquisition Cost When Paying Based On Compendia-Reported Prices.

Given the flexibility states have in determining Medicaid drug reimbursement, DOJ's suggestion that this Court can adjudicate DOJ's Medicaid-related claims on a unitary, national basis or as a matter of law is untenable. Indeed, where evidence has not been lost (or destroyed), Defendants' discovery efforts have revealed that individual states made varying policy decisions in determining payment rates for multiple-source drugs, including deliberate decisions to use "spreads" to subsidize dispensing costs and achieve other objectives.

[4] The HHS Departmental Appeals Board resolves disputes between HHS and outside parties such as state agencies, Head Start grantees, universities, nursing homes, doctors, and Medicare beneficiaries relating to HHS programs. (*Id.* ¶ 35.) As stated on its website, DAB's decisions represent the "final decision" of HHS. (*Id.*); *see also State of Nebraska, Dep't of Health and Human Services v. Dep't of Health and Human Services*, 435 F.3d 326, 330 (D.C. 2006).

(a) State Payment Rates Were Negotiated In The Political Arena.

Federal law requires Medicaid payment rates to be "sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." 42 U.S.C. § 1396a(a)(30)(A). To meet this "access" requirement, state Medicaid officials often negotiate directly with stakeholders—including legislators, governors, Medicaid officials, and providers.

DOJ has not even tried to demonstrate what any individual state program intended to pay for drugs, and its suggestion that each state intended to pay an estimate of acquisition cost for each drug reimbursed cannot be squared with reality. Examples abound:

- In 2001, Illinois advised CMS that "[o]ur drug cost methodology was derived via a two step approach which included 1) a thorough review of what other State's [sic] were doing and selecting the percentage off of AWP that was reasonable and 2) conducting negotiations with the Pharmacy Industry." (CF ¶ 58(a)).)
- When CMS challenged Idaho's drug reimbursement formula, the state explained: "Representatives from the state pharmacy association, hospital association, and retailer's association met with the Department numerous times *to negotiate reimbursement rates* for pharmacies." (*Id.* ¶ 58(b) (emphasis added).)
- New Jersey officials negotiated with providers "even back in the '80s," when they "sat across the table from professional organizations in the State, professional pharmacy organizations in the State" to "discuss our intentions regarding changes" in reimbursement. (*Id.* ¶ 58(c).)
- North Dakota's rate was "based solely" on what providers received from Blue Cross Blue Shield, and had nothing to do with estimating acquisition cost. (*Id.* ¶ 58(f).)

The record is clear that drug reimbursement rates do not attempt to estimate costs, but are instead the outcome of reasoned negotiations between the stakeholders, which properly balance the competing policy concerns. (*Id.* ¶ 58.) For example, a 1997 OIG study found that generic drugs were purchased 41.9% below AWP on average in Maryland. In response, Maryland decided not to change its AWP–10% payment formula "due to the possibility of strong objections from pharmacy providers." (*Id.* ¶ 59(c).) Similarly, California pharmacy

organizations defeated legislative efforts to increase the discount off AWP in that state's Medicaid payment formula. (*Id.* ¶ 59(h).) New Jersey did not increase its AWP discount because providers prevented New Jersey from doing so. (*Id.* ¶ 59(j).) The story in other states was the same. (*Id.* ¶ 59.)

Yet CMS *approved each of these negotiated drug reimbursement formulas*, regardless of whether the payments exceeded acquisition costs in the aggregate, let alone on a drug-by-drug basis. Federal officials explicitly conceded this reality in an internal decision memorandum (which the DOJ attempted to withhold based on assertions of privilege) entitled "Review of Medicaid Drug State Plan Amendments." The document recognized that Medicaid programs pay more than acquisition cost for drugs, particularly generics. (*Id.* ¶¶ 60-61.) It found that the "lesser level of discount [from AWP] is generally the result of negotiations that occur between the state and pharmacy representatives." (*Id.*) And it concluded that CMS will nonetheless "approve rates set by the legislature or through negotiations, *even if the rate differs from that suggested by other documentation, such as the rates of other states or from a state survey*." (*Id.*) (emphasis added). When shown this document, CMS's Pharmacy Team leader Deirdre Duzor acknowledged the obvious: "We knew that for generic drugs that AWP minus 13 was a generous payment based upon the IG's findings." (*Id.* ¶ 62.)

(b) States Did Not Rely on Compendia Prices As A Proxy For Acquisition Cost For Multiple-Source Drugs.

Every Medicaid witness to testify based on first-hand knowledge admitted that states knowingly paid more than acquisition cost for multiple-source drugs and often used the spread to further policy goals. They knew that Medicaid providers would make a "spread" (including so-called "mega-spreads") on multiple-source drugs reimbursed by Medicaid and believed that this

was permitted by state law.[5] For example:

- Florida's Jerry Wells knew by at least 1987 that AWPs for generics could exceed acquisition cost by "80 or 90 percent," and that the difference between AWPs and market prices for generics was "all over the map." (CF ¶ 1(i).)

- Michigan's Sandy Kramer knew "AWPs were upwards of 500 percent above acquisition costs" for generics by at least 1992. (*Id.* ¶ 1(d).)

- Illinois had concluded no later than 1994 that "AWP has become virtually meaningless as a real number, particularly for multi-source drugs." (*Id.* ¶ 1(j).)

- Georgia Medicaid officials knew that they were providing "a profit margin to providers in reimbursing them for the ingredient costs." (*Id.* ¶ 38(a).)

- Rhode Island's goal was "always" to "provide some margin over the actual purchase price for pharmacy providers." (*Id.*¶ 38(e).)

- Ohio's Robert Reid also saw a "clear distinction between trade name drugs and generic drugs"; he knew it was "not uncommon for there to be a wide, wide disparity between AWP" and acquisition cost for generics. (*Id.* ¶ 1(b).)

- Benny Ridout, North Carolina's Medicaid Pharmacy Director from 1972 to 2000, likewise knew "all through [his] career" that the "brand[] [AWPs] always had less markup on them than the generics." (*Id.* ¶ 1(c).)

- By the mid-1990s, Oklahoma's Nancy Nesser knew of a "wide difference" between AWP and acquisition cost for generics: "It wasn't like, with the brand name where you could—you can see it's consistent. . . . If you pulled two—even of the same generic drug, the—there's no consistency between the AWP and the acquisition." (*Id.* ¶ 1(g).)

- And when asked about a statement by NAMFCU and DOJ that Medicaid programs were required to pay no more than acquisition cost, Tennessee's Leo Sullivan bluntly stated: "You do that and you won't have a program." (*Id.* ¶ 38(f).)

State after state provided the same testimony. (*Id.* ¶¶ 1, 38.)[6]

[5] Defendants' individual briefs contain additional information on what state and federal officials understood about spreads for their individual drugs.

[6] *See also id.* ¶ 1(v) (Myers & Stauffer: agreeing that their contemporaneous reports for Medicaid programs revealed "a relatively tight distribution of the data points for single source drugs and a comparatively more diffuse, more variable distribution for multisource drug products").

(c) State Medicaid Programs Intentionally Paid A Profit On Multiple-Source Drugs To Encourage Generic Usage, Maintain Access, And Cross-Subsidize Inadequate Dispensing Fees.

The reasons state Medicaid programs chose to pay based on compendia prices varied. Some states permitted a margin to encourage pharmacies to dispense generics. To justify paying an average 44% profit margin on generics, Illinois reasoned:

> The [OIG] audit reports that pharmacies can purchase generic and brand name drugs for 65% and 22%, respectively, less than the wholesale price. In this rulemaking, DPA is increasing the percentage deduction from the AWP for generic drugs from 12% to 20% and brand names from 10% to 11%. When deducted from the percentage discount allowed for generic and brand name drugs (64% [sic] and 22%), an overall profit of 44% is made by the pharmacy when generic drugs are dispensed and 11% when brand name drugs are dispensed. *This profit disparity is another way this rule promotes the dispensing of generics over brand names*.

(CF ¶ 43(a).) The math is simple: Illinois saved money by allowing providers to make a higher "spread" on generics because, even with a higher profit margin, generics were cheaper.[7]

Other states permitted a margin to cross-subsidize inadequate dispensing fees. As the United States General Accounting Office reported in 1993: "HCFA and state Medicaid officials agreed that pharmacies must often use excess Medicaid reimbursements to cover their dispensing costs." (*Id.* ¶ 44.) As Minnesota's Pharmacy Program Director Cody Wiberg put it:

> You have to look at both sides of the equation. . . . We know AWP, "ain't what's paid." But if we move towards more transparency and we get closer to reimbursing on the ingredient side at what providers actually pay, then we have to look at the dispensing fee side in the case of pharmacies, *because we've always kept that below what we think the true cost of dispensing is to make up for the fact that there is some money being made on the ingredient side.*

(*Id.* 45(a) (emphasis added).) Georgia's Jerry Dubberly testified that his "wasn't the only state that was overcompensating providers on ingredient costs at the same time that they were undercompensating providers for dispensing costs." (*Id.* ¶ 45(b).) Delaware's 30(b)(6) witness,

[7] *See, e.g.*, CF ¶ 43; *id.* ¶ 43(a) (Tennessee's Leo Sullivan: "it's just so fundamental" that a state "would want to pay some profit on multiple-source drugs to incentivize their use").

Cynthia Denemark, knew that "providers relied upon a margin on ingredient costs . . . [to] supplement for the inadequate dispensing fee" that had been frozen by "budgetary constraints." (*Id.* ¶ 45(c).) She openly discussed this practice with other states as early as 1994. (*Id.*) Numerous other state witnesses deposed acknowledged that cross-subsidization occurred (*id.* ¶ 45), and Illinois' Ron Gottrich signed an Affidavit attesting to the practice. (*Id.* ¶ 45(e).)

Even DOJ's experts acknowledge cross-subsidization. In a 2002 report for California, Myers & Stauffer found a "typical" margin on ingredient reimbursement of $10, but noted that the margins "must be considered in tandem with an analysis of pharmacy dispensing cost and dispensing fee reimbursement in order to fully evaluate the issue of the adequacy of Medi-Cal pharmacy reimbursement." (*Id.* ¶ 49; *see also* ¶ 50.) Dr. Schondelmeyer concurs: "experts agree that Medicaid dispensing fees are low relative to actual dispensing costs," leading to cross-subsidization. (*Id.* ¶ 54.).

C. Multiple-Source Drug Payments Under Medicare.

1. CMS Always Interpreted "AWP" In Medicare Payment Rules To Mean Compendia-Published AWP And Not Empirical Averages.

Unlike Medicaid, Medicare had no separate outpatient drug benefit during the pertinent time frame, but rather paid for drugs only if they were administered incident to a physician's services. CMS was directly responsible for administering the payment.

Federal law set the rate at which CMS was obligated to make those payments. Between 1992 and 1997, regulations allowed CMS to pay providers the lower of the national "average wholesale price," "estimated acquisition cost," or the provider's billed charge. From 1998 until the passage of the Medicare Modernization Act of 2003 ("MMA 2003"), a federal statute directed CMS to pay providers the lower of 95% of "average wholesale price" or the provider's

charge along with a set dispensing fee.[8] These rules were addressed solely to CMS and its carriers. At no time prior to 2004 did CMS or Congress impose on manufacturers any obligation to report prices that would be used to calculate Medicare payment rates.[9]

CMS and Congress have always interpreted "average wholesale price" to refer to published compendia prices, and not actual averages of transaction prices, both under the 1991 regulations and under BBA 1997:

- Kathleen Buto, a CMS official who played a central role in drafting the 1991 regulations as the Director of the Bureau of Policy Development, agreed that the "national average wholesale price" language in that regulation was intended to refer to "the average wholesale price as published in Red Book and similar price listings." (CF ¶ 104(e).)

- Bruce Vladeck, the CMS Administrator from 1993 to 1997, testified that CMS always understood AWP as used in to both the 1991 regulation and the 1997 Balanced Budget Act to refer to "published average wholesale price." (*Id.* ¶ 104(a).)

- Nancy-Ann DeParle, CMS Administrator from 1997 to 2000, agreed that CMS "interpreted that to refer to the prices published in the Red Book and Blue Book." (*Id.* ¶ 104(b).)

- Tom Scully, who succeeded DeParle and held the position through the enactment of MMA 2003, testified that he understood "law and regulations" required the use of the published prices, even though he believed it was "stupid" policy. (*Id.* ¶ 104(c).)

- In 2000, when DOJ and HHS attempted to adopt the DOJ AWPs, which differed from compendia prices, 89 Members of Congress stated that AWP is "a term widely understood and indeed defined by [HHS] manuals to reference amounts reflected in specified publications." (*Id.* ¶ 122.)

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[8] CMS also had "inherent reasonableness" authority to reduce reimbursement for drugs to levels CMS believed to be more appropriate. *See Medicare Program; Application of Inherent Reasonableness to All Medicare Part B Services*, 63 Fed. Reg. 687 (Jan. 7, 1998).

[9] By contrast, the laws and regulations establishing the Medicaid rebate program required manufacturers to report to CMS the Average Manufacturer's Price ("AMP") and Best Price for drugs, giving detailed definitions and procedures for that obligation. 42 U.S.C. § 1396r-8(b)(3)(A), (k)(1). Likewise, MMA 2003 imposed on manufacturers an obligation to report to CMS their Average Sales Price ("ASP") for purposes of calculating Medicare payments. 42 U.S.C. § 1395w-3a(b); 42 C.F.R. § 414.904(b) (defining ASP for multiple-source drugs and explaining how to calculate it).

Every other federal official to testify agreed.[10] In fact, CMS issued annual Program Memoranda from at least 1998 through 2003 instructing agents to use "the AWP as reflected in such sources as Red Book Blue Book, or Medispan." (*Id.* ¶¶ 102, 107.)

2. There Are Genuine Issues Of Fact As To Whether Medicare Intended To Pay Actual Acquisition Cost.

In 2006 this Court ruled in another case that "average wholesale price" as used in the 1991 regulations and BBA 1997 has a "plain meaning," *see In re Pharm. Ind. Avg. Wholesale Price Litig.*, 460 F. Supp.2d 277, 278, 287-88 (D. Mass. 2006), which apparently required Medicare officials to pay by reference to "the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies." *Id.* at 278.

As the Court will recall, the DOJ led the Court to this ruling in Track 1 by submitting an *amicus* brief setting forth the purported position of HHS on the matter, which this Court "drew heavily from" in rendering its ruling. (Dkt. No. 3299 at 3 n.3.) The Government then invoked the Touhy Regulations, 45 C.F.R. § 2.1, to preclude the Track 1 defendants from introducing any evidence contradicting DOJ's self-serving handiwork. (*See generally* Dkt. Nos. 3239-41, 3281, 3353, 3372, 3383-85; Dkt. Orders of 10/20/2006, 11/21/2006.) After issuing its AWP ruling, and during the Track 1 trial, this Court recognized the potential for mischief with the DOJ's strategy of providing no witnesses, but only its own "*amicus*" say-so, as to HHS's position on that key issue. The Court put the question directly to the Assistant U.S. Attorney:

> Here's my concern, Mr. Henderson. . . . I'm likely to have a trial at some point down the road on the [DOJ] cases. What if I make a decision in this incredibly important case and I don't have the key Government witnesses? That seems a

[10] Dr. Robert Berenson, the Director of the Center for Health Plans and Providers and later Deputy Administrator from 1998 to 2001, testified that "there was a common understanding within the agency that AWP referred to prices in these compendia and that they deviated from actual acquisition cost and that's how we sort of viewed AWP." (*Id.* ¶ 104(h).) Other officials with direct responsibility for Part B drug issues testified similarly, as did the OIG officials who extensively analyzed Medicare drug payment issues. (*Id.* ¶ 104(f)-(k).) The Medicare carriers also testified that it was well established in the industry that AWP referred to compendia prices. (*Id.* ¶ 110.)

little like cat-and-mouse.

(*See* 11/13/2006 Tr. at 7.)

The record compiled in these cases amply confirms the Court's concerns. Discovery has demonstrated that CMS did not share DOJ's understanding. Instead, CMS officials paid based on compendia-published AWPs, with full knowledge that those prices were not acquisition cost, for a host of legitimate policy and political reasons having nothing to do with alleged fraud.

(a) CMS Knowingly Paid A Profit On Multiple-Source Drugs Reimbursed By Medicare Part B.

CMS knew about spreads on multiple-source drugs long before AWP was adopted as the basis for payment in 1991 and 1997. For example, more than a decade before these cases were filed, a HCFA Regional Administrator explained that the 25% discount applied to brands would be "insufficient" for "multi-source drugs" because the mark-ups on these drugs vary drastically. (CF ¶ 3(a).) Over the following decade, a parade of articles, reports, and studies reminded CMS that generics, unlike brands, are sold at a fraction of AWP. (*Id.* ¶¶ 3(b)-(j).)

The 1991 regulation, where CMS rejected a proposal to pay at 85% of AWP and instead adopted an undiscounted AWP methodology for Medicare, illustrates the point. In the preamble to the regulation,[11] a section titled "Effects of Separate Payment for Drugs" states:

> Under our final policy, carriers will be instructed to base payment for drugs on the lower of estimated acquisition cost or the national average wholesale price of the drug *as published in the Red Book and similar price listings*.

[11] In interpreting federal regulations, courts give great weight to language contemporaneously provided by the agency. *See Rucker v. Lee Holding Co.*, 471 F.3d 6, 12 (1st Cir. 2006) (according substantial weight to language contained in the regulation's preamble); *Wiggins Bros., Inc. v. Dep't of Energy*, 667 F.2d 77, 88 (Temp. Emer. Ct. App. 1981) ("It is well settled by decisions of this Court that the preamble to a regulation . . . should be considered in construing the regulation and determining the meaning of the regulation."). Courts have rejected attempts to ignore language in the preamble based upon a supposed "plain meaning" of a regulation. *See Vermont v. Thomas*, 850 F.2d 99, 103 (2d Cir. 1988) (rejecting petitioners' request to "have us ignore the preamble language in favor of the 'plain meaning' of the regulations") (citing *N.Y. State Comm'n on Cable Tel. v. FCC*, 571 F.2d 95, 98 (2d Cir. 1978) ("Mere incantation of the plain meaning rule, without placing the language to be construed in its proper framework, cannot substitute for a meaningful analysis.")); *Seneca Oil Co. v. Dep't of Energy*, 712 F.2d 1384, 1397 (Temp. Emer. Ct. App. 1983) (rejecting Department of Energy's "[c]urious[ ]" request to ignore preamble).

(*Id.* ¶ 95 (emphasis added).) The preamble also contained the following language:

> f. *Low osmolar contrast media (LCOM).* Divergent payments exist among carriers for LOCM, also known as non-ionic contrast material, for radiological studies. We will pay separately for LOCM if it is used for patients with specified characteristics under the *standard methodology for payment of drugs generally. That is, we will base payment on the lower of estimated acquisition cost or the published* wholesale price of the drug. The estimated acquisition costs will be determined based on carrier surveys of actual invoice prices paid by physicians.

(*Id.* ¶ 96 (emphasis added).) And in the regulation itself, CMS explicitly stated that it was well aware that "many drugs could be purchased for considerably less than 85 percent of AWP—*particularly multiple-source*." (*Id.* ¶ 94 (emphasis added).)

(b) CMS Intentionally Used Compendia Prices For Drugs To Cross-Subsidize Inadequate Professional Fees.

As with Medicaid, Medicare officials deliberately paid a margin on drugs to subsidize inadequate or non-existent dispensing fees. Former Administrator Scully forthrightly admitted that profits on drug payments were, in fact, cross-subsidizing practice costs. (CF ¶¶ 137, 141; *see also id.* ¶¶ 134-35.) A 1995 CMS Final Rule stated that "Payment for functions furnished by pharmacists is included in the amount that Medicare pays for the drugs." (*Id.* ¶ 136.) Contemporaneous statements confirm the practice. A 1998 trade publication reported that "Medicare officials would argue that the 'service component'" for infusion and inhalation drug suppliers was "'built into the [AWP-based] fee schedule'" for prescription drugs. (*Id.* ¶ 138; *see also id.* ¶ 140.) And OIG's Robert Vito recalled conversations with CMS about the fact that "respiratory [and] infusion providers relied upon reimbursement rates for drugs to cover services." (*Id.* ¶ 139.)

CMS recognized Medicare's use of drug profits to cross-subsidize elsewhere in the Federal Register:

- "[A] key purpose of the [MMA 2003] legislation was to eliminate the cross-subsidization of composite rate payments by drug payments." (*Id.* ¶ 148.)

- "Congress established the ASP based payment for inhalation drugs and separate authority for dispensing of these drugs for good reason, namely to pay appropriately for each service and to eliminate cross subsidization of services." (*Id.* ¶ 149.)

The changes wrought by MMA 2003 confirm that cross-subsidization was an animating concern for why Medicare intentionally and willingly paid an ingredient cost amount for certain Part B drugs significantly exceeding acquisition cost. Specifically, when Congress changed the Medicare payment rate from 95% of AWP to 106% of ASP for inhalation drugs, CMS simultaneously dramatically increased the corresponding dispensing fees for these drugs. For example, before MMA 2003 Medicare paid only a $5 dispensing fee for a 30-day prescription of ipratroprium bromide; when Congress abandoned the AWP methodology, CMS increased that fee by ten-fold, to $57, then fixed it at $33. *See* 42 U.S.C. § 1395u(o)(1)(A)(iv); *id.* § 1395u(o)(D)(i); (CF ¶¶ 142-47.) Moreover, for other drugs where MMA did not increase dispensing fees (including certain infusion drugs), Congress maintained the AWP methodology—which CMS continues to use *to this very day*. In the words of former CMS Administrator Scully, Congress exempted these drugs from the new ASP methodology in order to "freeze . . . some level of cross-subsidy." (CF ¶ 141.)[12]

Whether Medicare's cross-subsidization justifies the margin paid on Defendant's drugs will be hotly disputed at trial. After the Track 1 trial, this Court acknowledged Medicare cross-subsidization but found that "there was no evidence that any margin over the 20 to 25 percent industry-wide formula was needed to compensate doctors for their costs of administration for these drugs and risks like spoilage." *In re: Pharm. Industry Avg. Wholesale Price Litig.*, 491 F. Supp. 2d 20, 37-38 (D. Mass. 2007). Track 1, however, involved expensive branded drugs,

[12] Tellingly, CMS today interprets the direction from Congress to maintain AWP for infusion drugs to require use of AWPs published in the compendia, even though it results in payments much higher than ASP. (*Id.* ¶¶ 131-33.) This position cannot be squared with DOJ's litigating position. Indeed, the current director of the CMS division that sets Part B drug payment policies agreed that, if CMS wanted to pay acquisition cost for these drugs, he would "probably not" rely upon compendia prices. (*Id.*)

which are typically not discounted (because they typically have no substitutes). These cases involve relatively inexpensive generics; a 25% margin on a $10.00 product is just $2.50. Plus, for many of the cross-subsidized services here, which are much more labor-intensive than dispensing a pill, the fee paid by Medicare was not just inadequate but non-existent.

D. Medicare And State Medicaid Programs Intentionally Paid "Mega-Spreads."

The evidence in this case undermines the trope of the so-called "mega-spread." DOJ champions the notion that a large percentage difference between a published price and average acquisition cost constitutes dispositive evidence of fraud. But "mega-spreads" in this case are just a mathematical parlor trick to obscure small margins.

The Federal Government has acknowledged that margins should be measured in dollars, not percentages. This difference can have a profound impact on drug payment policies. A Congressional Budget Office report in 2004 stated that "the dollar markup is a better indicator of the size or adequacy of Medicaid's reimbursements to pharmacies than is the percentage margin." (*Id.* ¶ 40.) CMS's Dierdre Duzor recognized, "if you have a prescription that's a dollar and you have a hundred percent markup, that's only another dollar." (*Id.* ¶ 41(d).) Tellingly, when DOJ's experts, Myers & Stauffer, provide states with information about the average "margin" allowed on ingredient cost per prescription, they display the results in dollar terms, not percentages. (*Id.* ¶¶ 49, 53.)

Medicaid officials, too, measured spreads by dollars, not percentages:

- When DOJ asked Tennessee's Leo Sullivan about "1000% spreads," he countered that "a thousand percent makes headlines but doesn't mean anything if you don't have a dollar amount affixed to it." (*Id.* ¶ 41(a).)

- Minnesota's Cody Wiberg observed: "People don't spend percentages. They spend dollars." (*Id.* ¶ 41(b).) He agreed that a $7 spread on a $1 drug would be "consistent with the goals of the [Minnesota] Medicaid program" to pay a profit on the drug ingredient. (*Id.*)

- And Louisiana's M.J. Terrebonne testified that she did not feel Louisiana overpaid if it allowed an average margin on ingredient cost of $8 to $10 or $12 per prescription. (*Id.* ¶ 41(c).)

Viewed properly, then, the margins on the relatively inexpensive generic drugs at issue here are not "mega-spreads."

E. Repeated Rejections Of Attempts To Change the System Confirm Medicare And Medicaid's Intentions To Pay A Spread.

At trial, the jury's understanding of what Medicare and Medicaid intended to pay for drugs will be informed as much by what officials chose not to pay as by what they paid. Both programs repeatedly and deliberately chose not to pay at or close to acquisition cost.

1. CMS And Congress Considered And Rejected Paying Medicare Drug Claims At Actual Acquisition Cost.

Medicare has rejected acquisition cost reimbursement since at least 1991. Indeed, in October 1991, the OIG provided comments to CMS on its proposal to pay providers at AWP. The OIG had just conducted a study of invoice prices at CMS's request and concluded that drugs such as vancomycin were being purchased at a 75% discount below published AWPs. (CF ¶ 3(e).) If CMS wanted to pay no more than acquisition cost, OIG suggested, then CMS should require providers to bill the "lower of AWP for the specific drug used or the actual invoice price of the drug." (*Id.* ¶ 112.) CMS rejected that recommendation.[13]

CMS again considered (and rejected) paying acquisition cost rather than AWP in 1995, when Robert Niemann drafted proposed regulations to pay based on acquisition cost. (*Id.* ¶ 114.) Those regulations were never promulgated.

In 1997 and again in 1998, legislation was proposed that would have changed the Medicare payment system to pay based on acquisition cost rather than AWP. (*Id.* ¶ 115.) In a

[13] A more specific explanation for why CMS rejected OIG's recommendation will need to wait for trial, inasmuch as DOJ delayed producing the work papers for the 1991 OIG study until the end of discovery.

December 1997 radio address, the President urged Congress to adopt the legislation, partly because providers being reimbursed at AWP were "paying just one tenth" of that (a 1000% spread) for some drugs. (*Id.* ¶ 116.) Congress nonetheless went forward with 95% of AWP, and CMS knowingly continued to pay "mega-spreads" on multiple-source drugs.

At each of these junctures when Medicare chose AWP over acquisition cost the choice was knowing and deliberate. As former Administrator Vladeck testified, CMS was not "fooled into believing that it was paying actual acquisition costs." (*Id.* ¶ 117.)

2. Congress And States Rejected The DOJ's Attempt To Force Medicare And Medicaid To Pay Acquisition Costs As "AWP" For Certain Drugs In 2000.

Three years after Congress declined to adopt acquisition cost in favor of continuing to pay "inflated" AWPs for Medicare-reimbursed drugs, government officials (including some of the lawyers litigating this case) attempted to achieve the same result by promulgating the so-called "DOJ AWPs" for infusion and injectable drugs. Medicare and most Medicaid programs resoundingly rejected that effort, again deliberately choosing to pay allegedly "inflated" AWPs.

In May 2000, HHS Secretary Donna Shalala advised Congress that there were "significant discrepancies between the prices that Medicare must pay by law and the significantly lower prices at which physicians may obtain [certain] drugs." (*Id.* ¶ 118.) Accordingly, Shalala intended to cause Medicare carriers to use drug pricing information collected by DOJ in lieu of published AWPs. (*Id.*; *see also* 119-121; *see also id.* ¶¶ 123-24.)[14]

Congress reacted swiftly to these "DOJ AWPs." On July 28, 2000, 89 Members of Congress wrote Secretary Shalala to object to HCFA's plan to equate AWP with prices actually paid by physicians for drugs. (*Id.* ¶ 122.) They made clear their intent to cross-subsidize

[14] Susan Gaston, Health Insurance Specialist at CMS from 1991 to 2003, testified that the DOJ AWP effort was "the result of a litigation suit." (*Id.* ¶ 77.)

provider costs with drug profits, noting that AWP is "a term widely understood and indeed defined by [HHS] manuals to reference amounts reflected in specified publications." (*Id.*) Shortly thereafter, Congress explicitly barred the Secretary of HHS from "directly or indirectly decreas[ing] the rates of reimbursement" below 95% of AWP. (*Id.* ¶ 126.)

As to Medicaid, the "DOJ AWPs" took the form of strong recommendations to the various state programs that they use these "more accurate" data rather than published AWPs. (*Id.* ¶¶ 68-70.) Most states either rejected the recommendation outright or stopped using the "DOJ AWPs" shortly after they were promulgated. (*Id.* ¶¶ 71, 73.) Missouri, for example, stopped using the DOJ prices because its $4.09 dispensing fee "was not designed to cover [infusion] drugs" and "providers threatened to cease services due to insufficient dispensing fees." (*Id.* ¶ 74.) Similarly, California concluded that the "DOJ AWPs" would "result in dramatic decreases" in reimbursement and chose not to implement them "due to the serious impact on both the providers and beneficiaries." (*Id.* ¶ 79.)

Indeed, with respect to this "DOJ AWP" project, even CMS itself recognized that, because states "*authorized*" payment based on "*inflated AWPs*," it would be improper to characterize compendia AWP-based payments as "overpayments." CMS stated:

> The OIG concludes that because most states base their reimbursement for drugs on AWPs, inflated AWPs have 'caused Medicaid to overpay for these products.' (See pages ii (Conclusion) and 9 (first paragraph.)) *Since the regulations and relevant state plans authorize payment for drugs based on AWPs, regardless of whether those prices are inflated, we have concerns with the statement that states and Medicaid have 'overpaid' for drugs.*

(*Id.* ¶ 72) (emphasis added).

COMMON POINTS OF FACT AND LAW PERTINENT TO THE GOVERNMENT'S MOTIONS FOR PARTIAL SUMMARY JUDGMENT

I. THE GOVERNMENT MISSTATES THE IMPORT OF "GOVERNMENT KNOWLEDGE" EVIDENCE IN THESE CASES.

As the foregoing discussion demonstrates, juries in these cases could certainly conclude that the Federal Government and State Medicaid programs, far from being defrauded by compendia-reported prices, embraced them with eyes wide open to effectuate legitimate policy goals. This is the first case this Court has had before it where the factual record on these matters has been fully developed. The story is compelling.

DOJ wants to withhold all this evidence from the jury. Having no answer to it, DOJ does not even discuss the evidence, dismissively labeling it all a "government knowledge" defense that the Court should reject as a matter of law. Specifically, DOJ argues that this evidence relates only to *scienter*, and even then only where the Government and individual defendants had direct communication about compendia prices, the Government specifically approved them, and Defendants acted based on those conversations. (DOJBr. at 31.) That is not the law.

First, DOJ is wrong to assert that evidence of government policy bears only on *scienter*. It also bears on falsity. *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 682 n.8 (5th Cir. 2003) (en banc) (Jones, J. concurring) (besides *scienter*, government knowledge "is also bound up with whether the claim itself was false").[15] And it also bears on FCA causation and damages causation, which require proximate causation. *United States ex rel. Franklin v. Parke-Davis*, No. Civ. A. 96-11651-PBS, 2003 WL 22048255, *4 (D. Mass. Aug. 22, 2003); *see United States v. First Nat. Bank of Cicero*, 957 F.2d 1362, 1374 (7th Cir. 1992) (causation is established "[i]f the

[15] This Court has so held. *See Massachusetts v. Mylan*, 608 F. Supp. 2d 127, 148 (D. Mass. 2008) ("Government knowledge could conceivably be relevant to two elements of the FCA: the falsity of the claim and the defendant's state of mind."); *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F. Supp. 2d at 174 ("In some circumstances, the government's knowledge [of a fraud] effectively negates the fraud or falsity required by the FCA.").

government would not have made a financial commitment absent the claimant's false statement"); *United States v. TDC Mgmt. Corp., Inc.*, 288 F.3d 421, 428 (D.C. Cir. 2002) (damages are measured based on "what the government would have paid out had it known"). The authorities DOJ cites do not suggest otherwise.[16]

Second, explicit Government approval of pricing conduct is not required; acquiescence in a defendant's conduct can preclude FCA liability. *See, e.g., Southland Mgmt. Corp.*, 326 F.3d at 682 n.8 (Jones, J. concurring) ("[t]he government's knowledge *and acquiescence* in its contractor's actions" is "'highly relevant'" to determining FCA liability) (emphasis added). Acquiescence, of course, includes "tacit or passive acceptance" and "implied consent." *See* Black's Law Dictionary 26 (9th ed. 2009). Where the Government knew about allegedly fraudulent conduct, and paid anyway, that defeats FCA liability. *See United States ex rel. Englund v. Los Angeles County*, 2006 WL 3097941, *12 (E.D. Cal. Oct. 31, 2006) (granting summary judgment for defendants because "the Federal government knew what [defendant] was doing and *implicitly* approved of [defendant's] actions") (emphasis added); *Gudur v. Deloitte*, 512 F. Supp. 2d 920, 932 (S.D. Tex. 2007) ("where government officials *are informed* of the alleged falsity," it precludes "a determination that the government has been deceived").[17]

Third, there is no requirement that "government knowledge" must involve direct communications between a defendant and the Government to be relevant. *United States ex rel.*

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[16] *United States ex rel. Gudur v. Deloitte*, 512 F. Supp. 2d 920, 932 (S.D. Tex. 2007), does not address the relationship between government knowledge and falsity, much less state that such evidence is irrelevant to the falsity inquiry. And *United States ex rel. Longhi v. Lithium Power Technologies, Inc.*, 513 F. Supp. 2d 866 (S.D. Tex. 2007) expressly references Fifth Circuit law that explicitly holds government knowledge—which may be in the form of acquiescence—*is* relevant to falsity. *Id.* at 883.

[17] The Government's reliance on *United States v. Lachman*, 387 F.3d 42 (1st Cir. 2004), is misplaced because *Lachman* neither concerns the FCA nor addresses the impact of government knowledge evidence upon an FCA analysis. *Lachman* concerned the Export Administration Act of 1979 ("EAA"), a criminal statute; the sole issue addressed was whether a term used in EAA regulations was unconstitutionally vague. *Id.* The quote from *Lachman* cited in DOJ's brief regarded agency interpretations of a specific regulation; it in no manner concerned whether, in an FCA case, formal Government approval is necessary to negate *scienter*. *Id.*

Burlbaw v. Orenduff, 548 F.3d 931, 954 (10th Cir. 2008) ("[N]either the directness of the government-contractor communications nor their nexus to an existing contractual relationship constitute an essential predicate for the government knowledge inference."). Where the Government is fully informed of large-scale spreads but, as a policy matter, continues to use a payment system incorporating those spreads, that vitiates an FCA claim.[18] There is no requirement that government knowledge come from communication with a defendant; in determining that "a government knowledge defense [was] viable" in *Mylan*, for example, the Court rested its conclusion on an OIG report. 608 F. Supp. 2d at 150, 152.[19] Nor is there any requirement that the government explicitly communicate approval to a defendant, let alone that a defendant rely on such explicitly communicated approval; "actual reliance" is not part of the analysis. *See, e.g., In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F. Supp. 2d 164, 174 (D. Mass. 2007).

Finally, the law does not require the degree of specificity DOJ suggests. When Medicaid (or Medicare) programs choose to continue paying claims based on AWPs, *after* learning of the purported "inflated" nature of AWPs, government knowledge may negate elements of the FCA. *See Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 152 (D. Mass. 2008) ("[A] government knowledge defense is viable because the government decided to continue using WACs as a policy matter.").

* * *

[18] It also is relevant to whether Defendants' conduct was "unjust," a requisite showing for DOJ's unjust enrichment claims.

[19] Indeed, such a requirement would be nonsensical under the facts of these cases. The Government's mechanical application of case law pertaining to instances where there is contractual privity or other *direct* obligations between the Government and the defendant is inapplicable under these circumstances, where the Government had no binding agreements with manufacturers regarding AWP. There could be no reason, in these cases, for a manufacturer to contact the Government for "approval" over a non-existent contractual or regulatory duty. The Court's ruling in *Mylan* recognizes the appropriate distinctions between this case and the Government's inapposite authorities.

In short, evidence pertaining to government policy choices applies much more broadly to defeat FCA claims than DOJ suggests. Especially when viewed in the light most favorable to Defendants, the evidence set out above (and expanded upon in the individual Defendants' briefs) shows extensive government awareness and continued approval of payments for generic drugs exceeding acquisition costs. This precludes summary judgment for DOJ.

II. THE GOVERNMENT IS NOT ENTITLED TO SUMMARY JUDGMENT ON ANY ELEMENTS OF ITS FCA CLAIMS.

DOJ's requests for summary judgment as to the FCA elements of falsity, *scienter*, causation, and materiality must each be denied for additional reasons, as well.

A. The Government Is Not Entitled To Summary Judgment On Falsity.

DOJ seeks summary judgment as to falsity based on the simplistic contention that, if a published AWP is something other than some (undefined) form of an empirical average wholesale price, it is "false" for purposes of the FCA. But DOJ's failure to cite any authority requiring Defendants to publish an AWP, let alone defining how to calculate it, dooms its request.

1. The Government Cannot Prove Falsity Because Defendants Did Not Violate Any Statutory, Regulatory, Or Contractual Duties.

A defendant cannot submit a false claim without objectively violating a "law, regulation, or other source" dictating that the claim is false.[20] Accordingly, to establish falsity as a matter of law, DOJ must show that each published AWP was false in comparison to some objective standard. DOJ cannot do this because AWP was never defined—and is *still* not defined—by any statute, regulation, or contract that governs Defendants. As a result there was, at a minimum, ambiguity and legitimate room for dispute over what AWP in compendia should have reflected. That, too, requires denial of summary judgment—for falsity is not established where a

[20] *See, e.g.*, *United States v. Prabhu*, 442 F. Supp. 2d 1008,1032-33 (D. Nev. 2006); *United States ex rel. Swafford v. Borgess Med. Ctr.*, 98 F. Supp. 2d 822, 828 (W.D. Mich. 2000); *United States ex rel. Cox v. Iowa Health Sys.*, 29 F. Supp. 2d 1022, 1026 (S.D. Iowa 1998).

defendant's conduct can be reasonably interpreted as authorized under the pertinent statute, regulation, or contract.[21]

Because the FCA is a "quasi-criminal," punitive statute that provides for automatic trebling, *see, e.g., Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784-86 (2000), it is not a proper vehicle to address statutory and regulatory noncompliance. *See, e.g., United States ex rel. Swafford v. Borgess Med. Ctr.*, 98 F. Supp. 2d 822, 828 (W.D. Mich. 2000). Any doubts about whether "the FCA can be stretched to implicate [a defendant's] conduct should be construed *against* the Government[.]" *Caremark, Inc.*, 2008 WL 3978086 at *17 (emphasis added); *see also United States ex rel. Atkins v. McInteer*, 345 F. Supp. 2d 1302, 1304 (N.D. Ala. 2004). Accordingly, falsity must be analyzed in the evidentiary context related to the duty claimed to have been violated. *See, e.g., United States ex rel. Farmer v. City of Houston*, 523 F.3d 333, 341 (5th Cir. 2008).[22]

Unlike every case cited by DOJ, the Government never articulated, in either law or

[21] *See, e.g., United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) ("[D]ifferences in interpretation growing out of a disputed legal question . . . are not false under the FCA."); *United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742 (N.D. Tex. 2003) ("[T]his evidence shows that it was unclear what products could be billed under code E0277 and that the defendants' use of code E0277 for the ROHO Mattress overlay was not false or fraudulent . . . ."); *United States ex rel. Ramadoss v. Caremark, Inc.*, No. SA-99-CA-00914-WRF, 2008 WL 3978086, *14 (W.D. Tex. Aug. 27, 2008) ("Because of this existing legitimate disagreement over the broad and imprecise language of the Medicaid, HIS, and VA statutes, Caremark's application of restrictions pursuant to its clients' plans does not subject it to FCA liability."); *see also United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376-77 (4th Cir. 2008) ("[T]he question of whether KBR performed sufficient maintenance under the contract represents, at the very least, 'a disputed legal question' about the 'inefficient management of [one's] contractual duties.' This is precisely the sort of claim that courts have determined not to be a false statement under the FCA"); *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1477 (9th Cir. 1996) ("Even viewing Hagood's evidence in the most favorable light, that evidence shows only a disputed legal issue; that is not enough to support a reasonable inference that the allocation was false within the meaning of the [FCA]"); *see generally* 1 John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.03[B] (3d ed. 2009).

[22] Recent FCA case law illustrates the point. In *United States v. Medica-Rents, Co.*, the court rejected the Government's attempt to "simplify the issue of whether the defendants submitted false or fraudulent claims" based on an improper HCPCS code, and granted summary judgment on falsity because "the scope of [the HCPCS code] was, at best, unclear and ambiguous" as was "evident by the contradictory instructions and guidance given by both HCFA" and the Medicare carriers. 285 F. Supp. 2d at 770-71. Likewise, in *United States ex rel. Ramadoss v. Caremark, Inc.*, the court rejected the Government's falsity argument because "[t]here was (and still is) a good-faith disagreement over a complex area of law regarding whether a plan restriction could be applied, applying the existing restriction is not a false statement or record under the FCA . . . ." 2008 WL 3978086, at *14.

contract, any guidance as to how AWP should be calculated. In 1989, two years before the Government adopted AWP for reimbursement in Medicare, OIG noted that "AWP is not a meaningful figure." (CF ¶ 3(c).) Six years later, an HHS lawyer admitted to Ven-A-Care that AWP was not defined. (*Id.* ¶ 101.) In 1999, Donna Shalala, the head of HHS (with direct reporting authority to the President), explicitly told Congress that "*AWP is not a well-defined concept nor is it regulated in any way.*" (*Id.* ¶ 100.) And in 2001, GAO publicly announced that the "*term AWP is not defined in law or regulation,* so the manufacturer is free to set AWP at any level, regardless of the actual price paid by purchasers." (*Id.* ¶ 103); *see generally supra* at 4-11, 13-17 (no one thought AWP was acquisition cost).

Key CMS and OIG administrators repeatedly confirmed that no authority governed how AWP should be calculated. For example:

- Dennis Smith, CMS's most senior official with respect to Medicaid, testified that "[AWP] is not further defined in law or regulation . . . . There is no definition, precise." (*Id.* ¶ 109(b).)

- Thomas A. Scully, the Administrator of CMS from May 2001 through January 2004, testified that AWP was "air" and "a stupid policy." (*Id.* ¶ 104(c).) As Administrator of CMS, he did not believe that claims paid based on published AWPs were "fraudulent"—a sentiment expressed by President Clinton years earlier. (*Id.* ¶ 116.)

- Robert Vito, one of the OIG's head auditors in charge of assembling OIG reports on AWP stated that AWPs could not even be properly audited by the OIG because there is no regulatory or statutory definition that defines what it is, much less what a manufacturer must do: "I've testified before Congress that AWP is not defined, not auditable . . . ." (*Id.* ¶ 109(a).)[23]

Yet Medicare used AWP for the drugs at issue here until 2003 (and still uses it for some drugs). Even today CMS allows states to use AWP in Medicaid payment formulas, often with minimal discounts. (*Id.* ¶¶ 60-64.) And it fully permits the use of AWP in reimbursing all generic drugs

[23] OIG recognized that even the Medicare law itself was incoherent on this point. In October 1991, the OIG provided comments to CMS noting that the preamble to the 1991 regulation "uses the term 'published wholesale price' while the regulation[']s text uses the term 'national average wholesale price.'" OIG stated, "We believe separate terminology may lead to confusion." (*Id.* ¶ 97.)

in Medicare Part D, notwithstanding "mega-spreads." (*Id*.)

By contrast, Congress and CMS imposed unambiguous duties on manufacturers as to AMPs in 1991, the same year that Congress adopted AWP for Medicare reimbursement. AMPs have a statutory definition grounded in empirical data: "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail class of trade." *See* 42 U.S.C. § 1396r-8(k)(1). The statute and supporting regulations require calculation of AMP without regard to "prompt pay" discounts that manufacturers give to retailers, but include other discounts and chargebacks. *See id*.; 42 C.F.R. § 447.504.[24] From this statutory framework, Defendants had no reason to conclude that a publicly available AWP referred to an actual average of prices net discounts, rebates, and chargebacks because a different term that CMS maintained as confidential, AMP, did.

At the very least, the meaning of AWP was ambiguous.[25] Indeed, it is telling that in a lawsuit alleging that the Government was misled by AWPs, DOJ fails to cite a single document or shred of testimony from any CMS official who actually shares DOJ's litigation theory that AWPs should have reflected acquisition cost.

DOJ's theory of falsity is particularly weak as to the allegedly false Medicaid claims. As DOJ has itself recognized, the "states—not the Federal Government—set the rate at which they pay pharmacies." (CF ¶ 22.) States are required to establish payment rates sufficient to assure

[24] In 2003, Congress again demonstrated its ability to clearly define pricing terms by statute. The MMA defined "average sales price" ("ASP"), as "the manufacturer's sales to all purchasers . . . in the United States for such drug or biological in the calendar quarter" divided by "the total number of such units of such drug or biological sold by the manufacturer in the quarter." 42 U.S.C. § 1395w-3a(c). The statute specifically provides that "[i]n calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than [Medicaid rebates to states])." 42 U.S.C. § 1395w-3a(c)(3)

[25] This Court's independent expert confirmed that "inconsistent and ambiguous information exists even currently concerning what type of price AWP measures." *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 460 F. Supp. 2d at 285.

that Medicaid recipients have equal access to care. 42 U.S.C. § 1396(a)(30)(A). As set out above, payment rates codified in state law resulted from extensive negotiations with providers to assure access to care, not because they believed, intended, or expected those rates would pay the "best estimate" of "estimated acquisition cost" for generic drugs. These states rejected attempts to align the "AWP discount" with empirical data from OIG and others, even though this continued the practice of paying "mega-spreads." As detailed above, states permitted a profit on ingredient cost to assure access to care, subsidize insufficient dispensing fees, promote the use of generics, and for other political goals. These programs acted consistent with the governing federal regulations, which measured drug payments only "in the aggregate" and explicitly permitted states pay margins on individual drugs.

To prove falsity for any individual Medicaid claim under the theory of this case, DOJ must provide evidence of what Medicaid officials in each state knew, what they expected compendia prices to represent, and how Defendants knowingly subverted that expectation. Indeed, for Medicaid, DOJ would have to show these elements state by state. *Cf. Mylan*, 608 F. Supp. 2d at 132-34. DOJ has not even attempted that. Nor has DOJ offered any evidence that any state, much less all states, paid more than they expected and authorized through their statutes and regulations. That is why CMS itself recognized that characterizing payments based on knowingly "inflated AWPs" as "overpayments" is inaccurate: "Since the regulations and state plans authorize payment for drugs based on AWPs, regardless of whether those prices are inflated, we have concerns with the statement that states and Medicaid have 'overpaid' for drugs." (CF ¶ 72.)[26]

[26] Although DOJ contends for purposes of the FCA that CMS Forms 37 and 64 are "claims" submitted by State Medicaid programs to the Government for payment, nowhere does DOJ explain what about these state-submitted Forms was false or fraudulent. (*See* DOJBr. at 13.) CMS Forms 37 and 64 are obligations imposed upon the individual States, not manufacturers. In fact, DOJ admits that if the Government believes that it has "overpaid a

* * *

In sum, if Congress, CMS, and state Medicaid officials did not understand what AWP meant (at least according to DOJ's definition), then the Defendants cannot be expected to have done better. Such ambiguity precludes a finding of falsity as a matter of law.[27]

2. This Court's Prior Decisions Do Not Support Finding Falsity As A Matter Of Law.

DOJ asks the Court to apply, mechanically and wholesale, its prior rulings in different cases. That will not do. DOJ cannot satisfy its obligation to point to contemporaneous guidance about the meaning of AWP by citing this Court's recent judicial interpretations of a statute directed to HCFA and Medicare carriers. *See Caremark, Inc.*, 2008 WL 3978086 at *14 (finding that a recent Sixth Circuit decision outlawing defendant's practices did not convert those practices into false claims at the time defendant acted).

Moreover, these decisions are distinguishable.[28] In rendering its Track 1 decision, this Court sat as a trier of fact in a case involving branded drugs and claims by Medicare

(continued…)

state based on [CMS's] review of the Form-64 or otherwise," the Government can seek to offset future federal payments to the State. Moreover, consistent with the federal regulation's "in the aggregate" provisions, the Forms 37 and 64 simply contain a line item for a state's quarterly expenditures for all drugs, including both ingredient costs and dispensing fees. DOJ has offered no evidence that any state's combined expenditures for any quarter, "in the aggregate," were overstated. Indeed, even after being made aware of these cases, CMS's 30(b)(6) designee testified that, even today, he is not aware of any evidence that the states were paid more than permitted by the federal regulations. (CF ¶ 30.) Without a false *claim*, of course, there can be no FCA liability. *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995) ("[T]he statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.'"); *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 71 (D.D.C. 2007) ("The FCA is not a catch-all anti-fraud provision; it only goes after claims that are false, not claims that are submitted while fraud is afoot.").

[27] The Government's reliance on the OIG's 2003 guidelines is unavailing. These guidelines explicitly stated that they were not intended as a rule and that they did not create any "new law or legal obligations." (*Id.* ¶ 109(c).) Indeed, had the OIG intended for its guidelines to obligate manufacturers to supply fully discounted AWPs to the drug pricing compendia, OIG would have not only overstepped its legal authority, but also supplanted express policy objectives of Congress and CMS. Tellingly, the OIG guidelines made no efforts to define AWPs.

[28] Indeed, this Court took pains to make clear that its Track 1 analysis, including its "plain meaning" analysis, does not apply to these cases. (*See* Dkt. No. 3299 at 2 n.1 ("On July 27, 2006, the Judicial Panel on Multidistrict Litigation transferred a *qui tam* action, in which the United States government has intervened, brought against pharmaceutical manufacturers under the False Claims Act. The Court does not address those actions here.").)

beneficiaries only. This case, in contrast, was brought by the Federal Government to recover sums it paid on comparatively inexpensive generic drugs under Medicare and Medicaid. Whether the AWPs for the products at issue in Track 1 were "deceptive and unfair" was measured against the Massachusetts Consumer Protection Act, which (unlike the FCA) does not require an objective untruth. *See* M.G.L. 93A § 2. Plus, the "unfairness" prong of the Consumer Protection Act has no counterpart in the FCA. *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 491 F. Supp. 2d at 95. Finally, in the Track 1 case, DOJ's "*amicus*" brief purporting to set forth "HHS's position," and subsequent invocation of the Touhy regulations, deprived the Court of the discovery obtained in this case that demonstrates that neither CMS nor state Medicaid officials believed that AWP in any way reflected acquisition cost.[29] And in the Massachusetts case, this Court held that even if a pricing term has a plain meaning, falsity must be addressed "drug-by-drug." *Mylan*, 608 F. Supp. 2d at 144. Here, DOJ has made no effort to make drug-by-drug determinations.

Indeed, these decisions, while involving different defendants, drugs, and laws, actually dictate denial of summary judgment because each hinged on the evidence presented about expectations. *In re Pharm. Ind. Avg. Wholesale Price Litig.*, 491 F. Supp. 2d at 39-41, 76-78, 86-9. In those cases, evidence established expectations for branded drugs. DOJ has put forward no evidence of expectations for the generic drugs here. And the evidence DOJ ignores makes clear that no one—in Medicare, any state's Medicaid, or otherwise—expected AWP to be actually acquisition cost. CMS, as its former Administrator Vladeck bluntly put it, was "not fooled." (CF ¶ 117.)

[29] The record developed in these cases has demonstrated DOJ's "amicus brief" (purporting to set out what CMS knew and understood AWP to mean) to be demonstrably false. It should be withdrawn.

B. The Government Is Not Entitled To Summary Judgment On *Scienter*.

DOJ's *scienter* arguments similarly overreach. Even putting aside the extensive "government knowledge" record that vitiates this element, DOJ's motion fails on its own terms. *Scienter*, which is ordinarily reserved for the finder of fact,[30] cannot be decided now.

To prove *scienter*, the Government must show with undisputed evidence that Defendants knew (or were reckless in not knowing) that published AWPs were supposed to reflect acquisition costs. *See, e.g.*, *Farmer*, 523 F.3d at 338. "[T]he *mens rea* requirement [of the FCA] is not met by mere negligence or even gross negligence." *Id.*; *see also United States ex rel. K&R Ltd. P'ship v. Mass. Housing Fin. Agency*, 530 F.3d 980, 983-84 (D.C. Cir. 2008). The Supreme Court recently explained that, where a defendant's reading of a statute, contract, or regulation is "objectively reasonable," it lacks *scienter*, *see Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 69-70 & n.20 (2007), and that applies equally to the FCA.[31] And again, DOJ must demonstrate *scienter* state-by-state for Medicaid claims. *Cf. Mylan*, 608 F. Supp. 2d at 132-34. DOJ's showing is

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[30] *See Mylan Labs.*, 608 F. Supp. 2d at 154 ("[I]t is unusual to grant summary judgment on *scienter* except in cases where the nonmoving party rests merely upon conclusory allegations, improbable inferences, and unsupported speculation.") (internal quotations omitted); *see also United States ex rel. Taylor-Vick v. Smith*, 513 F.3d 228, 231 (5th Cir. 2008) ("It is indeed well-settled . . . that we hesitate to grant summary judgment when a case turns on a state of mind determination."); *U.S. v. Taber Extrusions*, LP, 341 F.3d 843, 846 (8th Cir. 2003) (summary judgment inappropriate if the issue turns on defendant's *scienter*); *United States ex rel. Koch v. Koch Indus., Inc.*, 57 F. Supp. 2d 1122, 1129 (N.D. Okla. 1999) ("[T]he 'knowingly' prong of the FCA is one of fact, and should be decided by the finder of fact at trial and not prematurely decided on summary judgment.").

[31] *See, e.g.*, *K&R Ltd. P'ship*, 530 F.3d at 983-84 ("At bottom, K & R and MassHousing simply disagree about how to interpret ambiguous contract language. Given that and K & R's inability to point to anything 'that might have warned [MassHousing] away from the view it took,' there is no genuine issue as to whether MassHousing knowingly presented false claims to HUD." (quoting *Safeco*, 551 U.S. at 70)); *United States ex rel. Quirk v. Madonna Towers, Inc.*, 278 F.3d 765, 768 (8th Cir. 2002) (affirming summary judgment granted to defendant where plaintiff could not prove deliberate indifference based on testimony that hospital never sought legal advice or an opinion from Medicare regarding an improper billing practice its employees considered "acceptable standard procedure"); *United States ex rel. Rose v. E. Tex. Med. Ctr. Reg. Healthcare Sys.*, No. 2:05 CV 216, 2008 WL 4056601 at *5 (E.D. Tex. Aug. 25, 2008) (granting summary judgment to defendant because plaintiffs could not prove *scienter* under the FCA where both parties had reasonable interpretations of an ambiguous regulation); *United States ex rel. Kersulis v. Rehabcare Group, Inc.*, No. 4:00-CV-00636, 2007 WL 294122 at *4 (E.D. Ark. Jan. 29, 2007) (granting summary judgment to defendants, finding that plaintiffs had not produced adequate evidence of *scienter* where it was "undisputed that prior to 2002, CMS never issued formal guidance to either the provider community or to fiscal intermediaries"); *see generally* 1 John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.03[C], at 2-201 - 2-205 (3d ed. 2009).

woefully inadequate.

DOJ puts forward no evidence at all that Defendants believed that they were required to report acquisition costs, or that they reported AWPs with knowledge that the Government (or anyone) believed them to be acquisition costs. Nor has DOJ shown with undisputed evidence that Defendants' understandings of AWP were something beyond grossly negligent (assuming *arguendo* that there was some statutory, regulatory, or contractual authority requiring AWPs to be reported as some measure of actual market prices—and, as CMS and state Medicaid officials testified, there was not). *See K&R Ltd. P'ship*, 530 F.3d at 983-84; *Medica-Rents*, 285 F. Supp. 2d at 770; *Borgess Med. Ctr.*, 98 F. Supp. 2d at 828. Defendants' interpretation of AWP was not "objectively unreasonable" given the "dearth of guidance and the less-than-pellucid statutory text": "This is not a case in which the business subject to the Act had the benefit of guidance from the courts of appeals . . . that might have warned it away from the view it took." *Safeco*, 551 U.S. at 70. Indeed, the first decision adopting a "plain meaning" interpretation of AWP did not surface until 2006, and even that ruling was limited to an interpretation of authority that bound CMS, not manufacturers. Nor does DOJ try to explain how a practice consistent across an entire industry could be "reckless" as to interpretation of non-existing regulatory requirements regarding published AWPs. *Cf. Cox*, 29 F. Supp. 2d at 1025 ("A standard billing practice within an industry could hardly be said to be false, when no controlling authority requires parties to submit claims" in a certain way); *see generally* 1 John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.06[C][1], at 2-210.6 (3d ed. 2009).[32]

Moreover, here, like in *Mylan*, there is record evidence that Defendants believed AWPs

[32] The ambiguity surrounding AWP was exacerbated because Congress simultaneously codified AMP as an average manufacturer's price net discounts and other rebates. Even with reported AMPs in hand, CMS continued to pay based on compendia AWP for Medicare, and to approve state Medicaid plans based on AWP. A jury could conclude that it was reasonable for Defendants to believe that they were not required to report AWP as acquisition cost. *See K&R Ltd. P'ship*, 530 F.3d at 981 ("Is this fraud, or is it . . . just confusion?").

were at most undiscounted benchmarks, not empirical averages of acquisition cost, and they used them as such, "as well as some evidence that some others understood [AWP] the same way." 608 F. Supp. 2d at 154-55. Even if DOJ had evidence of *scienter*, it is at best materially disputed—and that defeats summary judgment.

C. The Government Is Not Entitled To Summary Judgment On Causation Or Materiality.

Causation is generally reserved for the jury, *Staelens v. Dobert*, 318 F.3d 77, 79 (1st Cir. 2003), and cannot be determined on summary judgment here. Nor can materiality. Again, for Medicaid, DOJ would have to show these elements state by state. *Cf. Mylan*, 608 F. Supp. 2d at 132-34. It has not even attempted that.

The FCA penalizes "any person who . . . *causes to be presented*, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1) (emphasis added). This requires proximate causation, established only where a defendant's conduct was a "substantial factor" in causing the submission of a false claim, and the circumstances are such that the law will impose liability. *See Franklin*, 2003 WL 22048255, at *4; *United States ex rel. Drescher v. Highmark, Inc.*, 305 F. Supp. 2d 451, 460 (E.D. Pa. 2004).[33] Defendants are not liable for false claims attributable to an intervening cause. *United States ex rel. Cantenkin v. Univ. of Pittsburgh*, 192 F. 3d 402, 416 (3d Cir. 1999). Similarly, materiality requires that a statement "has a natural tendency to influence, or is capable of influencing, the decision of the decisionmaking body to which it was addressed." *Mylan*, 608 F. Supp. 2d at 152-53 (emphasis added).

DOJ's argument is simplistic: Had Defendants not reported allegedly false prices to

[33] Whether Defendants "caused" the submission of false claims under § 3729(a)(1) should not be confused with whether Defendants' conduct "caused" damages, on which Defendants are moving for summary judgment. DOJ concedes that the appropriate causation standard for whether Defendants "caused" the submission of a false claim is a proximate cause standard, even though it applies the wrong standard in its arguments. (DOJBr. at 6.) DOJ's arguments concerning "but-for" causation are limited to causation of damages, and are in any event wrong. DOJ's theory that claims can be "infused with fraud" under these circumstances is untenable under the FCA.

pricing compendia, false claims would not have been presented or paid. (Dkt. No. 6319 at 18.) That is at best a "but-for" causation argument; it does not establish proximate causation or materiality as a matter of law.[34]

First, evidence indicates that the Government and state Medicaid programs, not Defendants, were the proximate cause of the submission of the allegedly "false claims" to the Medicaid and Medicare programs. Defendants do not set payment rates for Medicare or Medicaid. Payment for Medicare is set by Congress and CMS. Payment for state Medicaid programs is set by the states, subject to CMS approval. As discussed above, federal and state officials have understood for decades that published AWPs substantially exceeded acquisition costs for generic drugs. They relied on these spreads to incentivize generic substitution, compensate providers for inadequate dispensing fees, or otherwise ensure access. CMS used these AWPs in Medicare until 2003, and it continues to approve state Medicaid payment methodologies based on AWPs to this day. A finder of fact could reasonably conclude that these policy choices were the proximate cause of any "false claims" being paid, and that the relationship of acquisition cost to AWPs was not material to any allegedly false claim.[35]

Second, prior to 1998, federal regulations required that Medicare reimburse the lower of "the estimated acquisition cost" of a generic drug or "the median price for all sources of the

[34] DOJ's reliance on this Court's decision in the California case, on a motion to dismiss, is misplaced. There, the Court simply held that, for the purposes of pleading a claim under the California FCA, the causal connection between the manufacturers' conduct and the presentation of a false claim was not broken merely because reimbursement claims were submitted by providers. *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F. Supp. 2d 164, 175 (D. Mass. 2007). Nothing in that decision supports DOJ's sweeping contention that merely reporting prices that do not reflect providers' acquisition costs to pricing compendia conclusively establishes causation as a matter of law under the FCA.

[35] Indeed, even Government officials believed that the reimbursement methodologies established or approved were the cause of the allegedly "false claims." For example, in his famous 1997 radio address, President Clinton remarked that AWP spreads of up to 1000% weren't "even illegal; *they're just embedded in the practices of the system.*" (*See id.* ¶ 116; *see also id.* ¶ 72 (CMS denies in 2001 OIG's conclusion that "inflated AWPs have 'caused Medicaid to overpay for [drugs]'").)

generic form of the drug." *See* 56 Fed. Reg. 59502, 59621 (Nov. 25, 1991). The "estimated acquisition cost" was to be determined by surveys of actual invoice prices. *See id.* DOJ admits that the surveys were never completed. (*See* Dkt. No. 6316 ¶ 10.) A jury could reasonably conclude that the relationship of acquisition cost to published AWPs was immaterial to any alleged falsity and that, instead, the Government's knowing decision to rely exclusively on published prices proximately caused payment of an "false claims" by Medicare.

Third, because Medicare paid for multiple-source drugs based on the median AWP, 42 C.F.R. § 405.517, a published AWP is material, and could proximately cause injury, only if it is at or above the median. *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, 491 F. Supp. 2d at 99 (holding that the defendant's AWP for a generic drug "could only possibly" affect the median, and hence Medicare reimbursement, if "[the defendant]'s AWP was at or above the median."). DOJ has not even tried to conduct that analysis here.

Fourth, of the millions of Medicaid claims at issue, DOJ *never* analyzed which were potentially subject to FUL or MAC prices. (Dkt. No. 6190 ¶¶ 275, 278.) DOJ's failure to show how CMS established FUL prices, or the manner in which each State Medicaid program established each of its MACs, precludes a finding of proximate causation or materiality.

From 1987 to 2006, the FUL regulation permitted the Government to establish a "federal upper limit" for qualifying generic drugs at 150% of the published price for the least costly therapeutically equivalent product. (CF ¶ 87.) Although most of the drugs in this case met the regulation's requirements, CMS sometimes did not establish a FUL for a particular drug, or removed a FUL for a particular drug, because of concerns about the availability of the drug. (*Id.* ¶ 89.) There was no formal guidance for how or when to not set, or to remove, a FUL for a

qualifying drug; this review was left to CMS's discretion. (*Id*. ¶ 90.)[36]

Similarly, MACs were frequently based not on published AWPs, but on the actual acquisition cost of generic drugs. (*Id*. ¶ 79.) Consequently, Defendants' AWPs could not influence those State Medicaid programs' calculations of MACs, nor the payment of the actual claim. And even for those states that used AWPs to establish MAC prices, there is no evidence here that such Medicaid programs used any of the Defendants' AWPs. Thus, when CMS chose not implement a FUL for a qualifying drug, or when MACs were used, a jury could reasonably conclude that a Defendant's AWPs were not material, and that CMS or the states were the proximate cause of the submission of "false claims."

Finally, materiality is also not established because DOJ has not shown (nor could it) that Defendants ever "addressed" AWPs to the decisionmakers for either the Medicare or Medicaid programs. *Mylan*, 608 F. Supp. 2d at 152-53. Unlike AMP and ASP, which were reported directly to the Government, compendia prices were reported *to compendia*.

III. THE GOVERNMENT IS NOT ENTITLED TO SUMMARY JUDGMENT ON VARIOUS OF DEFENDANTS' AFFIRMATIVE DEFENSES.

While DOJ suggests it is challenging myriad affirmative defenses (DOJBr. at 37 n.17), it makes no legal argument as to release, laches, or failure to mitigate. And as to those it does challenge, its arguments miss the mark.

A. Estoppel.

DOJ is wrong to argue that estoppel can never run against the Government when "public

[36] Moreover, FULs are supposed to be set based on the *lowest* published price, 52 Fed. Reg. 28648 (July 31, 1987), and AWPs were not the lowest of published prices. (*Id*. ¶ 91.) Sue Gaston, the CMS employee responsible for setting FULs from April 1991 through February of 2003, testified that CMS "wouldn't have used AWP" when establishing FULs because "[s]etting a FUL using the AWP wouldn't achieve the cost savings." (*Id.*; *see also id.* (the CMS employee responsible for setting FULs beginning in 2004 testified that she could not recall ever having set a FUL based on an AWP)).) So, if there was a FUL in place, published AWPs could *never* influence actual payment of the claim because the FUL was always *lower* than the published AWP.

funds" are sought. Because "government knowledge is relevant to and may defeat the defendant's 'knowing' presentation of a false claim," it is "inconsistent also to assert, as the [DOJ's] estoppel argument does, that government knowledge cannot in some circumstances deprive the government of a civil FCA remedy." *Orenduff*, 548 F.3d at 956 n.25. Indeed, even DOJ's own brief cites cases applying the defense in those circumstances. (DOJBr. at 39). For example, in *United States v. Fox Lake State Bank*, 366 F.2d 962 (7th Cir. 1963), the Seventh Circuit reversed an award under the FCA, holding that the government was estopped from asserting an FCA claim.[37]

And there are at least disputed facts as to whether the defense is established here. Estoppel "precludes a litigant from asserting a claim or defense which might otherwise be available to him against another party who has detrimentally altered her position in reliance on the former's misrepresentation or failure to disclose some material fact." *Portmann v. United States*, 674 F.2d 1155, 1158 (7th Cir. 1982). Throughout the relevant time period, the Government never told manufacturers what should be reported as AWP. State and federal officials repeatedly stated in publicly available documents that they believed AWPs for generic drugs had no correlation to providers' actual costs. Nonetheless, DOJ now seeks to premise liability under the FCA on a definition of AWP that was never articulated until years later by this Court. There is even evidence of misconduct, as the Government kept this lawsuit under seal for eleven years, while allowing FCA claims to accrue based on an understanding of AWP

[37] *See id.* at 965-66 (estoppel barred recovery where defendant bank allegedly submitted insurance claims to the Federal Housing Administration for defaulted home loans without disclosing that the loans had been made fraudulently on the claims form, but government in fact knew that an officer at its bank had made the loans fraudulently); *see also Orenduff*, 548 F.3d at 956 n.25 (noting that even if a "broad estoppel rationale should apply to cases in which the government seeks money against private persons, this rationale should not apply to a civil FCA action, which involves the possibility of treble damages liability" because such a case is not "merely one in which the government seeks to recover *funds spent contrary to the will of Congress*," but instead "the government in this case seeks punitive damages from private persons in excess of any recovery of its funds"); *U.S. ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 642-46 (S.D. Ohio 2000) (denying summary judgment as to estoppel and rejecting argument that estoppel does not lie against the government in an FCA case).

completely different from CMS's pronouncements, and standing idly by as evidence was destroyed. (*See* Dkt. Nos. 6096, 6109, 6254 (Defendants' spoliation motions).) A jury could reasonably conclude that the Government is estopped from advancing its FCA claims.

B. Waiver, Ratification, And Consent.

DOJ's arguments concerning waiver, consent, and ratification are equally baseless. DOJ's position appears to be that, regardless of CMS's policy determinations and course of conduct over these many years, DOJ is the only government agency that can make a final determination regarding the propriety of Defendants' price reporting practices. Of course, Congress and the states rejected this theory when DOJ tried to impose its "DOJ AWPs" nearly a decade ago. And it has not improved with age. The statutes DOJ cites, 31 U.S.C. § 3730(a) and 28 U.S.C. § 516, at most give the DOJ authority over the conduct of this lawsuit. They do not change the impact of another government body's actions on the claims in this case. *See Hughes Aircraft Co. v. United States*, 534 F.2d 889, 901-02 (Ct. Cl. 1976). To hold otherwise would lead to absurd results: It cannot be that nothing any branch of our democratically-elected government does has effect until blessed by the unelected lawyers at DOJ.

COMMON POINTS OF FACT AND LAW PERTINENT TO DEFENDANTS' MOTIONS FOR PARTIAL SUMMARY JUDGMENT

I. THE COURT SHOULD GRANT SUMMARY JUDGMENT ON DAMAGES ON CERTAIN CLASSES OF ALLEGEDLY FALSE CLAIMS.

A. The Court Should Grant Summary Judgment As To All Claims That Were Not Paid Based On A Published Compendia Price.

To avoid summary judgment, the Government must show, for each claim, that a Defendant's actions proximately caused damages. 31 U.S.C. § 3729(a); *Franklin*, 2003 WL

22048255, at *4. DOJ has not even tried to do that.[38] While the "acts" alleged are reporting compendia prices, DOJ assumes liability and seeks damages for *nearly every claim* in this case, *regardless* of whether they were paid based on a reported compendia price. Defendants should be granted judgment for claims not paid based on a compendia price, including U&C, MACs, or FULs.[39]

DOJ does not contend that there was anything false or fraudulent with these payment bases.[40] While DOJ asks the Court to reverse all its prior proximate causation decisions, and now adopt a "but-for" standard, DOJ offers no reason to do that, and there is none. (DOJBr. at 23.) Similarly, while DOJ suggests that FULs and MACs were "partial mitigation" (DOJBr. at 26), DOJ cites no evidence of that. To the contrary, FULs and MACs were set at levels deemed to be prudent, but enough to assure access, as required by federal law. (CF ¶¶ 79-80.)[41]

Finally, DOJ argues that what matters is not the actual basis for claim payment, but "whether a true or accurate AWP or WAC would have resulted in lower reimbursement for a specific NDC." Thus, DOJ asserts that because the "'lower of' methodology" used by some states to determine Medicare payment results in AWPs and WACs "still being relied upon in [States'] computerized algorithm, all payments—even those based on non-compendia prices—

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[38] DOJ advocates that this Court reverse its prior decision in *Franklin* and instead a adopt a "but-for" causation standard for damages. There is no basis for this radical reversal of well-established FCA case law.

[39] *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F. Supp. 2d at 180 (no damages available for claims paid based on California MACs); *Mylan Labs.*, 608 F. Supp. 2d at 148 n.4 (no damages available for claims paid based on Massachusetts MACs, FULs, and U&C).

[40] For example, in the Government's response to Dey's Statement of Undisputed Materials Facts, the Government does not dispute that certain states did not rely exclusively on published prices for setting MACs and further states that "[t]he Plaintiffs' theory of recovery and damages model are not based upon Dey's false price statements causing inflated MACs." (Dkt. No. 6297 ¶ 235.) Furthermore, the Government states that it is not proceeding on a "FUL theory of liability" (*Id.* ¶ 244) and that it is not the Government's contentions that the Usual and Customary charges submitted by providers are in any way fraudulent. (*Id.* ¶ 256.)

[41] The FUL, set at 150% of the lowest published price, has a built in spread. (CF ¶ 87.) Medicaid programs also set MACs with some profit margin contemplated. (*Id.* ¶¶ 79-80.)

are necessarily "influence[d]" by compendia prices. (DOJBr. at 24.) This is the same faulty "lower of" argument that this Court already rejected in the California litigation, and it should fare no better here. (*See* Dkt. No. 6816 at 15.) Moreover, DOJ provides no evidence that any state (let alone all of them) would have paid less even for claims based on MACs, FULs, and U&Cs had different compendia prices been reported. DOJ's own brief admits that not all states would have done so. (DOJBr. at 24 (arguing that some undefined "overwhelming number of states" would have paid less).) And DOJ's expert admits he simply "assumed" for all claims that, if lower compendia prices were reported, payments would have been based on those prices. (CF ¶ 86.) Evidence, not lawyer argument or expert assumptions, is required to avoid summary judgment. *Magarian v. Hawkins*, 321 F.3d 235, 240 (1st Cir. 2003).

For all these reasons, the Government should (on its best day) be limited to collecting damages, if any, for the particular claims that were actually paid based on the allegedly inflated compendia-reported AWPs and WACs of the drugs at issue in this case.

B. The Court Should Grant Summary Judgment As To Damages On All Claims Where The Government Relied On Flawed Expert Extrapolation.

Defendants are entitled to summary judgment on damages for all Medicare and Medicaid claims for which the Government's expert, Dr. Duggan, extrapolated damages instead of using detailed claims data or arrays, because (1) Dr. Duggan's extrapolation methodology is not reliable and (2) DOJ cannot prove the payment bases for the extrapolated claims. Pruning these unwinnable damages from this case now will significantly streamline proceedings going forward.

As to Medicaid, the Government seeks damages for nearly all 50 states in the three cases, but Dr. Duggan used complete state claims data for only 10 states (Abbott), 14 states (Dey), or 16 states (Roxane). (DOJBr. at 16.) This sample was selected in part because the Government

failed to obtain data from the others.[42] Even for these selected states, there were gaps in the data; Dr. Duggan looked to aggregate data to fill the gaps for between 6.5% and 17.9% of these claims. (Dkt. No. 6316 ¶¶ 150-52.) Then, Dr. Duggan extrapolated again, to come up with his damage calculations for the remaining states, again using no actual state claims data.[43] (*Id.*) Dr. Duggan's extrapolations fail to account for the differences in reimbursement methodologies between states, such as those states that calculate reimbursement on a WAC-plus methodology or those states that had aggressive MAC programs. Similarly, Dr. Duggan's extrapolations do not exclude payments made on bases other than AWP or WAC.[44] As a result, his extrapolated damage figures likely overstate the alleged damages.

As to Medicare, Dr. Duggan used the few pricing arrays he had available, extrapolated those within carriers to cover gaps, and then extrapolated to other carriers for which he had no arrays at all. There is no way to tell for extrapolated periods the impact, if any, that Defendants' prices had on setting a payment rate; the carriers and DMERCs had discretion to include or exclude certain products in arrays. (CF ¶ 111.) This, too, requires summary judgment for defendants. *In re Pharm Indus. Avg. Wholesale Price Litig.*, 491 F. Supp. 2d at 99 (pricing is "a legal cause of plaintiffs' injury only when reporting a true AWP would have actually shifted the

[42] DOJ admitted that every state, at least before it was destroyed, had claims data but that DOJ failed to obtain such data from all states. (11/13/2008 Tr. at 44:11-17 ("we just don't have it all, and we're unlikely to get much more").)

[43] DOJ's reliance on *United States ex rel. Loughren v. UnumProvident Corp*. is misplaced; while this Court there noted that "extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate," in that particular case, the Court determined the method to be unreliable. 604 F. Supp. 2d 259, 261 (D. Mass. 2009). The same is true here.

[44] The aggregate data either does not contain the payment bases (in the case of SDUD and some time periods for the SMRF/MAX data) or has other features which makes it impossible to determine the payment bases accurately. DOJ does not allege that the SDUD data contains payment basis information. (DOJBr. at 16). Despite stating without reservation that the SMRF/MAX data is claims level data (*id.*), DOJ does not dispute that SMRF/MAX's claims-level data is not available for all states prior to 1999, and does not include quantity for any state prior to 1996. (Dkt. No. 6297 ¶ 288.) Nor does DOJ dispute that the SMRF/MAX data is rounded and does not contain or separate out co-pays and the dispensing fee. (*Id.* ¶¶ 289-90.) This reduces the ability to accurately calculate payment bases where available in the SMRF/MAX data.

median").

DOJ's response, which wrongly conflates whether the Government needs to "produce millions of claims in court" with the need to use complete data, is irrelevant. (*See* DOJBr. at 25.) Defendants are entitled to summary judgment for all states and time periods where missing state level claims data makes it impossible to determine the payment bases.

C. The Court Should Grant Summary Judgment On All Medicaid Claims Not Paid Pursuant To Published, CMS-Approved State Reimbursement Formulas.

The basis of a state Medicaid program's payment for a specific claim is critical to DOJ's case because there must be a "causal link" between the defendant's actions "and the actual payment." *In re Pharm. Industry Avg. Wholesale Price Litig.*, 478 F. Supp. 2d at 181. This Court held in the Massachusetts case that, even if a State paid a Medicaid claim based on a defendant's published prices, there is no liability if that payment was not consistent with the CMS-approved Medicaid plan and the State's regulations—such as where AWP was used as a proxy for WAC. *Mylan*, 608 F. Supp. 2d at 147-48. DOJ's own expert recognizes that claims not paid based on an approved regulatory formula should be "drop[ped]" from any damages calculation. (Dkt. No. 6202 ¶ 284.) The result here should be no different.[45]

II. SUMMARY JUDGMENT IS REQUIRED ON UNJUST ENRICHMENT.

A. The Government's Untimely Unjust Enrichment Claims Must Be Dismissed.

Over two years ago this Court dismissed unjust enrichment claims against Dey because

[45] DOJ's statement (DOJBr. at 14-15) that it may seek "full damages" is irrelevant. Damages are not recoverable when the Government fails to provide evidence, whether the Government seeks to recover them in "full," "partially," or otherwise. And besides, the cases cited do not support recovery of what the DOJ calls "full damages." In *United States ex. rel. Anti-Discrimination Center of Metro New York v. Westchester County*, No. 06 Civ. 2860(DLC), 2009 WL 1108517, at *3 (S.D.N.Y. April 24, 2009), the court awarded full damages where the defendant provided "no tangible asset or structure," making benefit-of-the-bargain damages impossible. In *United States v. Mackby*, 339 F.3d 1013, 1019 (9th Cir. 2003), the court awarded full damages in a case where the defendant "was entitled to nothing because he was neither a doctor nor a physical therapist in private practice." There is no claim here that the providers did not provide the pharmaceutical products at issue.

common-law claims added for the first time in DOJ's complaint-in-intervention do not relate back to earlier relator complaints. *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, 498 F. Supp. 2d 389, 401 (D. Mass. 2007). That ruling applies with equal force to the Roxane and Abbott cases. All unjust enrichment claims accruing more than 6 years before DOJ intervened in each case should be dismissed. *See* 28 U.S.C. § 2415(a).

DOJ asserts that the recent Fraud Enforcement and Recovery Act of 2009 ("FERA") amendments revive these claims. (DOJBr. at 27-28.) Not so. Because "there is a presumption against retroactive legislation," amendments "extending a statute of limitations after the pre-existing period limitations has expired" generally will not "revive[] a moribund cause of action." *Hughes Aircraft Co. v. U.S. ex rel. Schumer*, 520 U.S. 939, 946, 950 (1997); *see also In re Enterprise Mortg. Acceptance Co., LLC, Secs. Litig.*, 391 F.3d 401 (2d Cir. 2005); *Quaak v. Dexia, S.A.*, 357 F. Supp. 2d 330, 336 (D. Mass. 2005) (collecting cases).[46]

To subvert this presumption, Congress must "clearly manifest[] its intent to the contrary." *Id.* at 946. There must be "a plain statement" of Congressional intent, *Goncalves v. Reno*, 144 F.3d 110, 127 (1st Cir. 1998), which is "unmistakable," *Lattab v. Ashcroft*, 384 F.3d 8, 14 (1st Cir. 2004). That does not describe the FERA amendments, which outside of limited exceptions apply only *pro*spectively. *See* P.L. 111-21 § 4(f) ("The amendments made by this section shall take effect on the date of enactment of this Act and shall apply to conduct on or after the date of enactment . . . ."). While DOJ pins its hopes to one of those exceptions, a FERA provision stating that "section 3731(b) of title 31, as amended by subsection (b) . . . shall apply to cases pending on the date of enactment," Pub. L. No. 111-21 § 4(f)(2), it is wrong, for three reasons.

[46] These concerns are especially troubling in an FCA case, *see Hughes Aircraft*, 520 U.S. at 949, where revived claims could entail treble damages. *Cf. Landgraf v. USI Film Prods.*, 511 U.S. 244, 281 (1994) ("Retroactive imposition of punitive damages would raise a serious constitutional question.").

First, that provision does not apply on its face. The old § 3731(b), which set out the FCA statute of limitations (under which this Court dismissed DOJ's unjust enrichment claims in the Dey case, finding no relation back), was not amended. Rather, the old subsections (c) and (d) were re-designated (d) and (e), and a new subsection (c) was added, dealing with relation back. It is that new subsection (c) that DOJ says now permits relation back. *See* Pub. L. No. 111-21 § 4(b). But nothing makes that new subsection (c) retroactive.

Second, even if it did, the provision DOJ cites is silent as to whether § 3731(c) may "retroactively apply to revive claims that were barred at the time of [FERA's] passage," *Quaak*, 357 F. Supp. 2d at 336. It could equally be read to permit only relation back of claims viable at the time of enactment. That is not an expression of Congressional intent "so clear that it could sustain only one interpretation." *See Lindh v. Murphy*, 521 U.S. 320, 328 n.4 (1997); *see, e.g.*, *Lieberman v. Cambridge Partners, L.L.C.*, 432 F.3d 482, 489 (3d Cir. 2006).

Finally, even if the FERA amendments were retroactive, and even if they could revive expired claims, they only permit FCA claims, not common-law claims, to relate back.[47] The new subsection (c) purports to "amend[ ]" only the FCA statute of limitations, *see* Pub. L. 111-21 § 4(b), not that of other causes of action. The FCA does not allow a relator to bring common law claims on behalf of the United States; it would defy logic to allow them to relate back to a complaint that could not raise them. *See United States v. Reagan*, No. Civ. 97-169-TUC-WDB, 1999 U.S. Dist. LEXIS 22287, at *14-15 (D. Ariz. Apr. 19, 1999); *U.S. ex rel. Wilkins v. N. Am.*

[47] This reading is also consistent with the legislative purpose of FERA. According to one of FERA's authors, the purpose of this amendment was to overrule *United States v. Baylor University Medical Center*, 469 F.3d 263 (2d Cir. 2006), by "clarifying that the Government's complaint in intervention or amended complaint will relate back to the date of the original *qui tam* complaint." 155 Cong. Rec. E1287, 1295, 1299 (daily ed. June 3, 2009) (statement of Rep. Berman). In *Baylor*, the only question was whether FCA claims could relate back to a relator's complaint. The Government did not appeal the district court's dismissal of its common law claims as time-barred. 469 F.3d at 267. The suggestion that FERA was "enacted to cure" a "split among courts" regarding the relation-back of common law claims misreads the legislative history, which addresses only FCA claims. (DOJBr. at 28 n.10).

Const. Corp., No. Civ. A. H-95-5614, 2001 WL 34109383, at *14 (S.D. Tex. Sept. 26, 2001). Nor does it help DOJ that subsection (c) states that "any" DOJ-added claim relates back. (DOJBr. at 28.) While "sometimes the word 'any' in a statute deserves an expansive application," "such a result must never be the result of a wooden, uncritical capitulation to the word itself," but should only "occur[] where the surrounding statutory language and other relevant legislative context support it." *ACLU v. Dep't of Defense*, 543 F.3d 59, 69 (2d Cir. 2008). As just explained, that is clearly not this case.

B. The Government Should Be Required To Elect A Remedy.

Finally, the Government must elect a remedy between its unjust enrichment and FCA claims. The Government does not dispute that its FCA claims present an adequate remedy at law. And while DOJ seeks to preserve all options (DOJBr. at 29), almost fifteen years into this case and with trial on the horizon, it is time for DOJ to fish or cut bait.[48]

CONCLUSION

DOJ's motion for summary judgment should be denied in its entirety. The Defendants' motions for summary judgment, as to the common issues discussed herein, should be granted.

[48] This Court has frequently granted summary judgment on unjust enrichment where a legal remedy is adequate, including in an FCA case, *see United States v. Buckley*, No. Civ. A. 0011632RWZ, 2005 WL 164287, at *1 (D. Mass. Jan. 25, 2005) (FCA case), and in a case in which treble damages were available, *see Ben Elfman & Son, Inc. v. Criterion Mills, Inc.*, 774 F. Supp. 683, 687 (D. Mass. 1991); *see also One Wheeler Road Assocs. v. Foxboro Co.*, 843 F. Supp. 792, 799 (D. Mass. 1994); *Taylor Woodrow Blitman Constr. Corp. v. Southfield Gardens Co.*, 534 F.Supp. 340, 347 (D. Mass. 1982). This Court's decision in *Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314 (D. Mass. 2005), which held that a *motion to dismiss* was not the appropriate stage to require such an election, only proves that this Court may require the Government to elect is remedy now. *See id.* at 324.

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CERTIFICATE OF SERVICE

I, Brian J. Murray, an attorney, hereby certify that I caused a true and correct copy of the foregoing COMBINED MEMORANDUM OF DEFENDANTS ABBOTT LABORATORIES INC., DEY, INC., DEY, L.P., DEY L.P., INC., AND BOEHRINGER INGELHEIM ROXANE, INC. AND ROXANE LABORATORIES, INC. IN OPPOSITION TO THE UNITED STATES' CROSS-MOTIONS FOR PARTIAL SUMMARY JUDGMENT to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 28th day of August, 2009.

/s/ Brian J. Murray
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